



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,256	08/27/2001	Sek Chuen Chow	GJE-73	2484

23557 7590 04/22/2003

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 04/22/2003

'S

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,256

Applicant(s)

CHOW ET AL.

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 3 and 6-10 are presented for reconsideration on the merits.

The amendment and extension of 1 month time filed on January 27, 2003, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over the WO Patent WO 95/12615 cite for reasons of record, note previous Office action of October 16, 2002, see pages 3-4.

Applicants' arguments submitted with the amendment filed January 27, 2003 are not deemed persuasive for these product claims. The argument that hookworm, like other animals produces a vast array of compounds of which finding and purifying a useful natural product therefrom is like looking for "needle in the haystack" is noted. However, the useful and advantageous pharmaceutical product defining a excretory-secretory (ES) product of the hookworm, *Necator americanus*, is clearly disclosed, note page 1, lines 10-20.

Also a carrier is clearly disclosed, note page 11, claim 4. The advantage of being capable of inducing cell apoptosis is noted, however, the product of the cited WO patent inherently possesses this capability. The advantage is an intrinsic property of the cited ES product of the cited WO patent. Applicants have provided no reason why the

Art Unit: 1651

disclosed ES product would not have this property. The pharmaceutical as claimed herein is also derived from human beings.

However, with respect to obviousness one of skill would have been motivated to isolate a ES product as claimed based upon the cited WO patent. As Applicants point out an array of pharmaceuticals can be produced from the hookworm as disclosed by the cited WO patent. One of skill in the art would have expected successful results and the product is at least suggested by the cited patent.

Also the intended use of the product as claimed does not distinguish the product as claimed because the product as disclosed may inherently possess this property. The compounds are identical or at least suggested and taught by the cited reference. Their intended use does not establish that the products as claimed are different from the cited WO patented disclosure.

Claims 3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Brophy et al. for reasons of record, note page 4 of previous office action as noted above.

The argument that the products as claimed do not have glutathione-S-transferase activity is noted, however, the claims do not exclude this activity. Applicants allege that there is no reason to believe that induction of apoptosis would be capable by the products of Brophy et al. However, Applicants have not provided sufficient reasons why apoptosis would not be a necessary consequence and an effect which would naturally flow from a ES product of this human hookworm. The products are clearly disclosed and it is believed by the examiner that all of the properties of the ES product as claimed

Art Unit: 1651

would logically flow and be a necessary consequence of the disclosed ES products of Brophy et al.

Claims 8-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brophy et al.

Applicants argument that the product is different and therefore, any use of it is not obvious from Brophy et al. However, the ES products are obtained from the same source, human hookworm, and there is no evidence provided by Applicants which shows that the product are different as noted above. Also Brophy et al. clearly teach protective immunity during infection as to be a viable use for the ES products. Note the abstract. Therefore, one of skill would have expected inflammation treatment using the ES product of Brophy et al. to provide successful results. The method claims remain prima facie obvious over Brophy et al.

Claims 8-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/12615 and Brophy et al, both cited above, in view of Kalinkovich et al, for reasons of record at pages 5-6 of the previous office action noted above.

The argument that T-cell apoptosis is unexpected is not persuasive since the product is clearly disclosed by the cited WO patent and Brophy et al, and further treatment of infectious tissues is disclosed by Brophy et al, as discussed supra and in the prior office action noted above. Also immune responses are clearly disclosed by Brophy et al. and Kalinkovich et al.

Thus, since apoptotic cell death is a natural progression of many immune responses in the presence of hookworms and at least from Brophy et al. their products,

Art Unit: 1651

it is deemed that one of skill would have expected treatment of inflammation to be successful. Kalinkovich et al. clearly disclose that T cell population changes are associated with increased apoptosis and are most probably related to persistent helminth infection. Thus, the motivation to select for ES products to treat inflammation is clearly suggested by the cited prior art combination and one of skill would be able to reasonably expect successful results.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 3 and 6-10 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vlasuk et al. for reasons of record, note previous office action, noted above, at pages 7-8.

Applicants' argument that there is no disclosure of their material having apoptotic properties is noted. However, the products of Vlasuk et al. are disclosed to be excretory/secretory of the human hookworm *Necator americanus*, and thus, the products are disclosed by the cited reference. Also the ES products of Vlasuk et al. are useful for treating conditions associated with cancer and would be capable of treating

Art Unit: 1651

the cancer along with its associated conditions since organ failure is prevented. Clearly the treating of cancer and inflammation if not taught, are at least, suggested by Vlasuk et al. Note col. 38, all lines, and specifically lines 15 and 44. By treating thrombosis cancer is treated as well because for example, its devastating effects such as organ failure would be remedied.

Applicants' arguments that the Vlasuk et al. does not disclose anti-cancer activity and anti-inflammatory activity are noted. However, the reference as noted above clearly teaches treating inflammation and at least suggests, if not teaches, treating cancer. Therefore, in the alternative the claims are rendered prima facie obvious over the cited prior art reference. The ES products as disclosed by the cited prior art would have been at least expected to provide successful results for treating cancer because tissue affected with cancer is disclosed as being treatable with the disclosed products of the cited reference. Treating inflammation is disclosed as well and if not anticipated by the cited reference is at least obvious therefrom this cited teaching.

Claims 3 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vlasuk et al. in view of Kalinokovich et al, both discussed above and of record in the last Office action, noted above, at page 8.

The arguments are not deemed persuasive for reasons noted above. Applicants arguments appear to state that since Vlasuk et al. is not obvious when taken alone for those reasons set forth above and of record, then Vlasuk et al. combined with Kalinokovich do not make the claims obvious either, however, this is not specifically set forth in their response. The examiner simply responds as set forth above that Vlasuk et

al. in combination with the Kalinokovich et al. clearly sets forth the motivation to use ES products to control cell apoptosis. One of skill would have expected successful results especially when taking Vlasuk et al. combined with Kalinokoivich because products of the human hookworm have been clearly associated with T-cell apoptosis.

The claims remain rejected for all of the reasons set forth above and of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on (703) 308-4245 from 9:30 to 6:00.

Art Unit: 1651

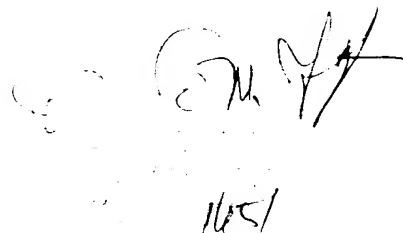
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.



Deborah K. Ware

April 19, 2003



1651